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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,049	01/17/2006	Jingyu Liang	2108.0060000/MAC	5056
26111 7590 05/14/2008 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER KEYS, ROSALYND ANN				
ART UNIT		PAPER NUMBER		
1621				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/531,049

**Applicant(s)**

LIANG ET AL.

**Examiner**

ROSALYND KEYS

**Art Unit**

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2007 and 13 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3,6,8 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,6,8 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/15/08 & 6/14/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of Claims***

1. Claims 2, 3, 6, 8, and 11-15 are pending.  
Claims 2, 3, 6, 8, and 11-15 are rejected.  
Claims 1, 4, 5, 7, 9 and 10 have been cancelled.

***Information Disclosure Statement***

2. The information disclosure statements submitted on January 15, 2008 and June 14, 2007 have been considered by the examiner.

***Response to Amendment***

*Specification*

3. The objection to the specification is withdrawn.

*Claim Objections*

4. The objection to claims 1 and 2 is withdrawn, due to the cancellation of claim 1 and amendment to claim 2.

*Claim Rejections - 35 USC § 112*

5. The rejection of claims 10 and 12 under 35 U.S.C. 112, second paragraph, is withdrawn.

*Claim Rejections - 35 USC § 102*

6. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) is withdrawn, since this claim has been cancelled.

***Claim Objections***

7. Claim 11 is objected to because of the following informalities: it does not end with a period. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not contain a written description of the treatment and prevention of a disease related to diabetes other than those disclosed in the first paragraph on page 4.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
13. Claims 2, 3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) in view of Sultana et al. (Phytochemistry, Vol. 50, 1999, pp. 1249-1253) or Page et al. (US 6,002,025).

Dittrich et al. teach that the compound 5-O-methyl-myio-inositol (sequoyitol) is found in the Taxaceae class and family of plants, but Dittrich et al. do not disclose a method of extracting said compound from said plants.

The steps and solvents disclosed in claims 2, 3, 6, and 8 are well known and are taught for example by Sultana et al. (see section 3.2 on pages 1251 and 1252) and Page et al. (see column 7, line 48 to column 9, line 2).

One having ordinary skill in the art at the time the invention was made would have found it obvious to extract the compound 5-O-methyl-myio-inositol (sequoyitol) from the Taxaceae class and family of plants as disclosed in Dittrich et al. by using well known steps and solvents such as those taught by Sultana et al. and Page et al.

Sultana et al. and Page et al. do not disclose that their columns are macroporous. However, one having ordinary skill in the art at the time the invention was made would have found it obvious to utilize a column having the pore size necessary for obtaining the desired separation.

14. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostlund et al. (US 5,550,166) in view of Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) and Oberley Free Radic. Biol. Med., 1988;5(2):113-24 (abstract) [online], [retrieved 2008-05-11]. Retrieved from the internet <URL: <http://www.ncbi.nlm.nih.gov/pubmed/3075947>.

Ostlund et al. teach the compound pinitol, compositions containing pinitol and its use in the treatment of diabetes (see entire disclosure, in particular column 1, lines 12 to 30 and column 3, line 11 to column 5, line 52). Pinitol is a stereoisomer of the claimed sequoyitol (see page 246 of Dittrich et al.). One having ordinary skill in the art at the time the invention was made would have found it obvious to utilize 5-O-methyl-myo-inositol (sequoyitol) in a composition for the treatment of diabetes, as taught by Ostlund, because compounds that are similar in structure are expected to have similar properties.

Ostlund et al. in view of Dittrich et al. do not teach the improvement in the metabolism of free radicals.

Oberley teaches that not only are oxygen radicals involved in the cause of diabetes, they also appear to play a role in some of the complications seen in long-term treatment of diabetes.

One having ordinary skill in the art at the time the invention was made would reasonably expect that based upon the teachings of Oberley, that treatment of diabetes and its complications in the manner taught by Ostlund et al. in view of Dittrich et al. would also involve treatment of free radicals which according to Oberley is a cause of diabetes.

#### ***Response to Arguments***

15. Applicant's arguments filed November 20, 2007 have been fully considered but they are not persuasive.

The Applicants arguments with regard to Dittrich, Sultana and Page have been considered but are not persuasive because the skilled artisan would reasonably expect to obtain more sequoyitol from a plant source that contained more sequoyitol (see Dittrich). The skilled artisan would reasonably expect that the extraction methods disclosed by Sultana and Page to be effective for removal of sequoyitol from the plant sources disclosed in Dittrich, since Page teach that their method is suitable for use on Taxanes, which is taught by Dittrich to be a source of sequoyitol and Sultana teach that their method is suitable for use on sequoyitol. The claim would have been obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." KSR International Co. v. Teleflex Inc., 550 U.S.\_\_\_\_, 82 USPQ2d 1385, 1395-97 (2007).

Thus, the Examiner believes that claims 2, 3, 6, and 8 are prima facie obvious.

The Applicants arguments with regard to Ostlund and Dittrich is not persuasive because the evidence used to rebut the prima facie case of obviousness is not sufficient because the compounds the Applicants used to attempt to show that the skilled artisan would not expect pinitol and sequoyitol to have similar properties are not as close in structure as pinitol and sequoyitol.

Thus, the Examiner believes that claims 11-15 are prima facie obvious.

### **Conclusion**

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSALYND KEYS whose telephone number is (571)272-0639. The examiner can normally be reached on M, R & F 5:30-7:30 am & 1-5 pm; T & W 5:30 am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROSALYND KEYS/  
Primary Examiner, Art Unit 1621

May 10, 2008